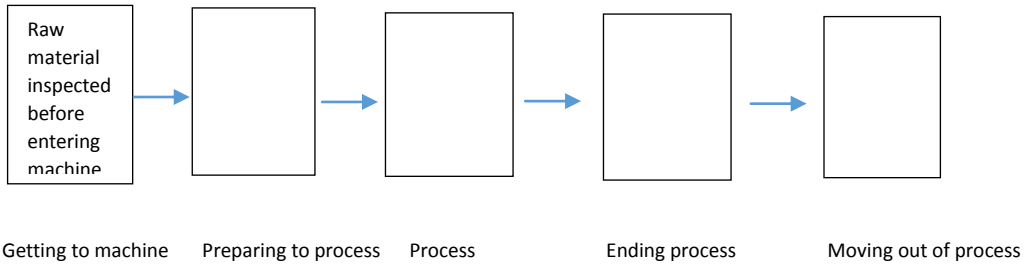
Effective FMEA's: A Window of Opportunity

By Karen Robertson, BS, M.Ed.

Failure Mode and Effects Analysis is a tool used by cross-functional teams to identify and fully understand any potential failures and why they occur, and how the failures impact the system. Any risks identified with the failure can be assessed from a number of viewpoints: product, design, machinery, process, maintenance, quality and safety, particularly in how the workers interface with the other viewpoints. When failures occur, people react in a variety of ways, and not with the usual pattern when all else is perfect. As an example, an operator on a machine generally works in the same pattern day to day. But, let's say that the machine is running a bit off, and so the operator changes what they do to accommodate the difference. This change in pattern increases the potential for injury. And this is where using an FMEA can help us understand where and when and how this can happen, and provide thoughtful intervention before an incident occurs.

In general, the benefits of completing FMEA's are not limited to risk alone. Completing an FMEA and investigating all the parameters of a process, including the product, machine, safety, etc. provides knowledge that can be used in other applications, such as training, the development of preventive maintenance programs and troubleshooting guides, standard operating procedures, lockout parameters, quality parameters, design improvements, or even diagnostic techniques.

Probably the biggest negative to the FMEA is that it is time consuming, and documents can get so large that they become unmanageable. Sometimes it's easier to break them into smaller bits, then tie the processes together later. The first step in completing an FMEA is to take the part of a process, a machine, a specific method, etc. and break it into component parts. Draw a simple flow diagram of the process, identify inputs and outputs, then break it into steps (nodes) based on the natural transitions in the process. For example:



From here, the detail will increase.

There is a lot of information that will be gathered in this process, so it is important that operators, engineers, maintenance, supervisors, safety personnel, quality personnel and other stakeholders be part of the process. These are the people with the information and experience. An FMEA cannot be done in isolation. If the right people are not present, the FMEA will not be as valuable.

Using a matrix like the one pictured below keeps the information organized so that it clearly defines where the failures and harm can come into play. Not every line is used, allowing for the expansion of information as the team sifts through each function, whether, process, the machine, methods used, man-machine interface, quality, product… again, combining all these functions provides a significantly greater comprehension of where and at what point in the process failures occur that impact safety.

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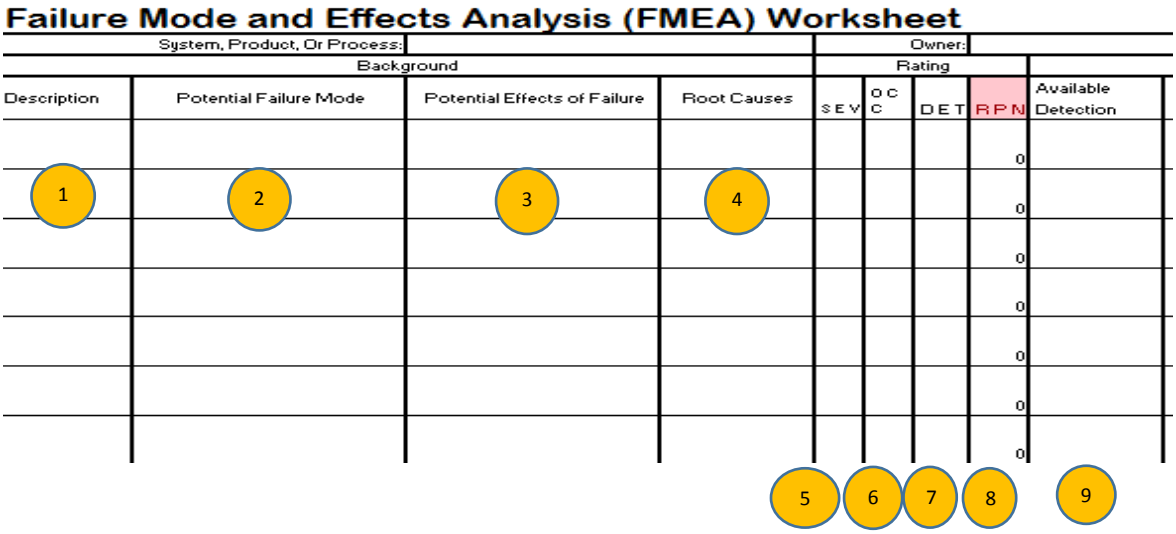

Explaining the Columns:

1- Description. Sometime written as "Step" or Task" This would be the *focus* of the project. The nice thing about this format, is that it can be changed, columns added to ensure the focus it there for a comprehensive analysis. You might add columns next to the Description column to accommodate this. Description can also list the function of the task or step as well.

2- Potential Failure Modes. Listed here is how the task/step/function can fail to meet the intended function/task/step or associated requirements. Here, failures such as "the function cannot be performed within the specified limits", "the performance of the function is poor or inadequate", "performance is intermittent", or "undesired/unintended issues occur".

3- Potential Effects of Failure. An effect is the consequence on the system or on the end user. There may be three levels here, so be cautious not to overlook the middle level, that of manufacturing.

4- Root Causes. Defines what might cause the "effect", or the reason the effect occurs. A Cause is determined by using the 5 Why technique. There can be many causes for each failure mode.

5- Severity. Most FMEA's have criteria that defines how significant a failure is. It will vary from place to place, so this is actually the first exercise the cross-functional team needs to define. It has to make sense for your operation. Severity is a relative ranking number determined without relevance to likelihood or detection. Usually a scale from 1-10, with 10 being the worst case. Note on this scale, any injury potential warrants a 9 or 10 ranking.

Example Severity Scale

FMEA SEVERITY (SEV) RATING	
Severity	Product/Process/Safety Criteria
None	No Effect.
Very Minor	Defect would be noticed by most discriminating customers. A portion of the product may have to be reworked on line but in station.
Minor	Defect would be noticed by average customers. A portion of the product (<100%) may have to be reworked on line but out of station.
Very Low	Defect would be noticed by most customers. 100% of the product may have to be sorted and a portion (<100%) reworked.
Low	Comfort/convenience item(s) would be operable at a reduced level of performance. 100% of the product may have to be reworked.
Moderate	Comfort/convenience item(s) would be inoperable. A portion (<100%) of the product may have to be scrapped.
High	Product would be operable with reduced primary function. Product may have to be sorted and a portion (<100%) scrapped.
Very High	Product would experience complete loss of primary function. 100% of the product may have to be scrapped.
Hazardous w/Warning	Failure would endanger machine or operator with a warning.
Hazardous w/out Warning	Failure would endanger machine or operator (danger or death) without warning.

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6-Occurrence (Likelihood). This is a measure of frequency. It is also a relative ranking number that the cross functional team must define and agree on prior to beginning the FMEA. Take into consideration the design life of the product, or how often the issue would occur in production. It is identified without consideration for severity or the likelihood of detection. Use units that are realistic for your operation. Likelihood is also limited in that prevention controls must already be in place or planned.

FMEA OCCURANCE (OCC) RATING				
OCC	Severity	Product/Process Criteria	Safety Occurrence	
1	Remote	1 in 1,500,00	Rarely Occurs	
2	Very Low	1 in 150,000		
3	Low	1 in 15,000	Occurs 1 x in 10 years	
4	Low Moderate	1 in 2,000		
5	Moderate	1 in 400	Occurs 1 x per year	
6	High Moderate	1 in 80	Occurs more than 1 x per year	
7	High	1 in 20	Occurs 1 x per month	
8	Very High	1 in 8	Occurs > 1 x per month	
9	Hazard	1 in 3	Occurs > 1 x per month	
10	High Hazard	>1 in 2	daily	

7- Detection. Detection is a ranking based on the type of controls that are currently in place. Controls can be administrative, or electronic based bells and whistles that alert the operator to failure. Again, the cross functional team must define what these are for the company.

An example: training/certification is an administrative detection, relying on the operator to notice and react to the failure. This might be a 7 on a scale of 9, with 9 being no detection is available.

FMEA DETECTION (DET) RATING		
DET	Severity	Criteria
1	Almost Certain	Current controls are almost certain to detect/prevent the failure mode.
2	Very High	Very High likelihood that current controls will detect/prevent the failure mode.
3	High	High likelihood that current controls will detect/prevent the failure mode.
4	Moderately High	Moderately High likelihood that current controls will detect/prevent the failure mode.
5	Moderate	Moderate likelihood that current controls will detect/prevent the failure mode.
6	Low	Low likelihood that current controls will detect/prevent the failure mode.
7	Very Low	Very Low likelihood that current controls will detect/prevent the failure mode.
8	Remote	Remote likelihood that current controls will detect/prevent the failure mode.
9	Very Remote	Very Remote likelihood that current controls will detect/prevent the failure mode.

With detection, it is important to understand that the detection method has to be relevant to prevent the failure.. An example: The pin is pulled from a hand grenade with a 10 second fuse. After 8 seconds the grenade is thrown into a room. It is detected, but everyone in the room is dead. An extreme example-- in this case the detection was irrelevant for one set of people, and harm was done.

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8- RPN (Risk Priority Number). Calculated by multiplying severity x likelihood x detection. The higher the number, the greater the risk, and the more focus should be placed on correcting the issue.

9- Here, document what detection is present or planned. This is helpful later if you need to know what is in place, so that efforts are not duplicated in corrective action plans. We can also use this to define maintenance priorities, based on the cumulative ranking.

Other uses:

The FMEA is the perfect planning tool as well. Using this as a "what if" exercise, a team can project what corrective actions would be the best fix. If needing to look at costs, your solution plan can weigh the cost of the corrective action vs. the expected RPN improvement. If designing new processes, this tool can be used to ferret out where bottlenecks might occur, or how a product might be impacted. It makes good business sense overall. Expand the matrix to fit your needs. See example below:

Failure Mode and Effects Analysis (FMEA) Worksheet

Page:		of																
System, Product, Or Process:				Owner:								Date:						
Background				Rating					Countermeasure				Results					
Description	Potential Failure Mode	Potential Effects of Failure	Root Causes	SEV	OCC	DET	RPN	Available Detection	Owner	Due/Done	Action	SEV	OCC	DET	RPN			
							0											
							0											
							0											
							0											
							0											
							0											

After corrective actions have been listed, and their owners, re-evaluate the correction to determine it's impact. Using this step, it will clearly show how much of a risk reduction you will likely get, and if the correction makes sense. From here, cost and feasibility of ease of implementation must be explored as well.